

SEP 18 1996

## 10. 510(k) SUMMARY

- (1) Lighthouse Medical, Inc.  
100 Beaver St.  
Waltham, MA 02154

Contact Person: Jenna Andelman  
Date Summary Prepared: March 12, 1996

- (2) Trade or Proprietary Name: FlexNeedle™  
Common Name: Intravascular administration set  
Classified Name: Intravascular administration set
- (3) Predicates: Luther Medical Products L-CATH for Ports (K# unknown)  
Medex SureCath Port Access Catheter (K# unknown)  
SIMS Deltec Gripper (K# unknown).

- (4) Description of Device:

The FlexNeedle™ is composed of a flexible catheter; a hub with elastomeric septum and side port; sideleg tubing with luer infusion fitting, cap, and pinch clamp; and an insertion stylet.

- (5) Intended Use:

The FlexNeedle™ allows transcutaneous cannulation of subdermally implanted venous access ports.

- (6) The FlexNeedle™ has the same technological characteristics as the above predicate devices in that it is a hollow tube with a luer fitting intended to remain in a subcutaneous access port in order to provide access to the bloodstream.